In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1958V

UNPUBLISHED

ANGELA QUINN CROSS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: December 2, 2022 Special Processing Unit (SPU); Ruling on Entitlement; Findings of Fact; Severity; Localized Injury to Shoulder; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA)

John Leonard Shipley, Davis, CA, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLMENT[1]

On December 26, 2019, Angela Cross filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration ("SIRVA") after receiving an influenza ("flu") vaccine on September 12, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters ("SPU").

[1] Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After a full review of the evidence, I find it most likely that Petitioner's injury was limited to her left shoulder; that the injury and its residual effects lasted for more than six months; and that she is otherwise entitled to compensation.

I. Relevant Procedural History

After the case's initiation and SPU assignment, the parties attempted to settle the claim, but by July 2021 they informed me they had reached an impasse in their negotiations. ECF No. 24; ECF No. 25. I therefore at Petitioner's request set deadlines for the filing of briefs addressing her entitlement to compensation. ECF No. 26.

On August 8, 2021, Petitioner filed a Motion for Ruling on Record. ECF No. 27. On September 7, 2021, Respondent filed his Rule 4(c) Report and Response to Petitioner's Motion, recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 29. Specifically, Respondent argued that (1) Petitioner had not established the statutory "severity" requirement of six or more months of injury-related sequelae, and (2) Petitioner had failed to establish that she suffered the Table injury of SIRVA, because Petitioner's pain was not limited to the shoulder in which she received the vaccine. ECF No. 29 at 8-11 (citing Section 11(c)(1)(D)(i); 42 C.F.R. § 100.3(c)(10)(iii)). Petitioner filed a Reply brief on September 14, 2021. ECF No. 30. This matter is ripe for my resolution.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See* Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed.

Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g*. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Relevant Factual Evidence

I have reviewed all evidence filed to date, but limit my discussion below to the evidence most relevant to my determination of whether Petitioner experienced the seqeula of her injury for more than six months, and whether Petitioner's "pain and reduced range of motion are limited to the [left] shoulder in which the intramuscular vaccine was administered." Section 11(c)(1)(D)(i); 42 C.F.R. § 100.3(c)(10)(iii).

A. Medical Records

- On September 12, 2018, Petitioner received a flu vaccination in her left shoulder from Rite Aid Pharmacy. Ex. 3 at 1.

- On September 24, 2018 (12 days after vaccination), Petitioner was seen by Kathryn Martin, PA, for a "[r]eaction to flu shot." Ex. 4 at 54. The medical record indicates that Petitioner presented with "left shoulder pain, which started after receiving a flu shot on 9/12/2018 at Rite Aid. She states that she thought the flu shot was given too high, and she points directly to the acromi[on], stating it was given there." *Id.* The records further indicates that Petitioner's "pain radiates down to the left elbow and sometimes across the left shoulder to the neck. No numbness or tingling. Has decreased range of motion of the left shoulder due to the pain. No pain in the neck or previous issues in the neck." *Id.* The record also details the Petitioner does "office work. No heavy lifting or repetitive lifting." *Id.* Ms. Martin assessed Petitioner as suffering from "[a]cute pain of left shoulder." *Id.* at 55.

- Petitioner returned to see Ms. Martin on October 5, 2018, for a "[f]lu shot injury." Ex. 4 at 52. The medical records indicates that Petitioner presented "for follow-up of her left shoulder pain, which started after receiving a flu shot to the area on 9/24/2018." *Id.* The record details that the "[p]ain is located within the shoulder joint. No history of previous issues to the left shoulder, and no precipitating injury besides the flu shot. She does office work and has been resting the shoulder since

last visit." *Id.* Ms. Martin again assessed Petitioner as suffering from "[a]cute pain of left shoulder." *Id.* at 53.

- On October 22, 2018, Petitioner was seen again by Ms. Martin for a "flu shot reaction." Ex. 4 at 50. The record states Petitioner presented for a "follow-up of left shoulder pain" which began after receipt of a flu vaccine on September 12, 2018. *Id.* The records notes that Petitioner "had been thinking about the shoulder injection," discussed at the last visit, and would now like to receive it. *Id.* It was further noted that pain had "flared up a few days ago when she had to drive four hours" and that her "pain is intense with lifting the arm" and that "holding the steering wheel with the left arm for extended periods of time exacerbates the pain." *Id.* Ms. Martin's notes also indicate that the "pain is mostly to the left shoulder, and sometimes radiates down the left upper arm and over left shoulder blade." *Id.* Petitioner was again assessed by Ms. Martin with "[a]cute pain of left shoulder" and a steroid injection was administered to her left shoulder to treat her pain. *Id.* at 51.

- Petitioner moved to Billings, Montana in November 2018, and began transitioning her medical care to the Department of Veteran Affairs (the "VA") in Billings. Ex. 2 at 123. She had an initial visit with a nurse on December 18, 2018, where her vitals and prescriptions were recorded, and screenings for depression, alcohol use, vaccinations, and PTSD conducted. *Id.* at 116-121. A physical examination was not conducted, nor was her shoulder pain mentioned.

- On March 19, 2020, Petitioner underwent a mammogram at Community Care, a non-VA related program. Ex. 2 at 109. The following day, Petitioner was seen outside the VA for a rash on her left shoulder and abnormal vaginal bleeding at the Billings Clinic. Ex. 5 at 22-29. These records contain no discussion of Petitioner's left shoulder pain.

- Petitioner next treated for her left shoulder pain on April 21, 2019, when she presented to Nancy Beckman, APRN, at the Billings Clinic, for "left shoulder pain for several months." Ex. 5 at 16. The record notes that Petitioner received "a flu shot in October, states it was given in the joint and her arm went limp in 2 days, she was then seen three more times, treated with pain medication and a steroid injection in the left shoulder joint. This injection was very helpful in alleviating the pain." *Id.* The record describes that Petitioner "present[ed] with pain in the left shoulder, deep in the shoulder, pain from the shoulder to the palm, no weakness or numbness. She is right handed and works with arms over head sometimes and can't raise her arm." *Id.* Ms. Beckman assessed Petitioner with left shoulder pain and administered a Toradol injection to treat her shoulder pain. *Id.* at 18-19.

- On May 1, 2019, Petitioner was evaluated by Orthopedics PA, Lanny Schneider, for left shoulder pain. Ex. 5 at 7. It was noted that Petitioner had recently moved back to the area and was establishing care with Ms. Beckham. *Id.* The record further documented that Petitioner reported "she has had ongoing shoulder pain since about September 2018. She [is] relating this to a flu shot that she states went into the joint. She was seen about 3 times in her past hometown. . . . Apparently she responded well to a cortisone injection, but did not get any physical therapy." *Id.* Ms. Schneider noted that Petitioner described "pain today for me at the shoulder on the lateral side with some radiation down to the elbow, but nothing beyond that. She states it is difficult to raise her arm above her head, sometimes. She does feel like the cortisone shot did help considerably but did 'wear off.'" *Id.* In her assessment, Ms. Schneider noted "[i]t is difficult for me to [s]ay whether problems now are related to the previously mentioned flu shot. It seems like this is more of a rotator cuff[,] tendonitis[,] bursitis type of thing, more associated with her job and overhead lifting." *Id.* at 8. Ms. Schneider recommended physical therapy which she indicated Petitioner was going to try and administered another steroid injection. *Id.*

- Petitioner continued to treat thereafter for her shoulder injury. Petitioner was evaluated by orthopedic surgeon, James Elliot, MD, on March 16, 2020. Dr. Elliot's history of Petitioner's left shoulder pain describes an onset of left shoulder pain "almost immediately after she got a flu shot." Ex. 10 at 20. He notes she "complains of left shoulder pain mostly lateral and anterior" and indicates she "has no radiation of pain down her arm . . . . no numbness and tingling in her left extremity. She never had any neurologic symptoms in her left upper extremity following the incident. Symptoms were restricted to pain only in the left shoulder. She denies any neck pain." *Id.* Dr. Elliot notes an MRI impression of a 50% partial tear of Petitioner's left rotator cuff. Ex. 10 at 21-22. Prior to undergoing shoulder surgery, Dr. Elliot recommended she undergo an EMG to rule out Parsonage-Turner syndrome. Ex. 10 at 22.

- Petitioner underwent an EMG on March 25, 2020 of the left upper extremity. A history described Petitioner's "pain in her left shoulder and difficulty using left shoulder in September 2018 after a flu shot. Onset was abrupt and she has had continued left shoulder and upper arm pain." Ex. 10 at 23. The EMG revealed no evidence of Parsonage-Turner syndrome or cervical radiculopathy. An "incidental finding of electrical median mononeuropathy at or near the wrist (carpal tunnel syndrome)" was noted as asymptomatic. *Id.* at 23-24. After reviewing her EMG, that same day, Dr. Elliot noted an impression of "[o]ngoing issues with h[er] left shoulder. No true neuro[logical] component to this." Ex. 10 at 19.

- Petitioner subsequently underwent left shoulder surgery and further physical therapy to treat her left shoulder. Ex. 9 at 15-16; Ex. 11.

B. Declarations

Petitioner and her husband, Sean Cross, executed signed and sworn declarations describing the onset and sequela of Petitioner's shoulder injury. Ex. 6; Ex. 7. They describe the onset of Petitioner's pain as immediately following her September 12, 2018 flu vaccine. Ex. 6, ¶4; Ex. 7, ¶ 4.

Petitioner explains that her October 22, 2018 steroid injection did provide temporary relief of the pain she was experiencing in her left shoulder. Ex. 6, ¶¶ 11-12. Petitioner further explained that in November 2018 she moved to Billings, Montana from California. Ex. 6, ¶ 13. She continued to experience pain in her left shoulder, and as a veteran was attempting to transfer her care to the local VA clinic in Billings. Ex. 6, ¶¶ 14-15. In the interim, she treated her shoulder through self-care to include limiting use of her shoulder and performing stretching and other exercises recommended by her previous provider. Ex. 6, ¶ 14. Ultimately, her pain grew severe enough that on April 21, 2019, she sought care outside the VA (where she still could not get an appointment) at the Billings Clinic where she received treatment for her shoulder until she was able to receive care at the local VA hospital in Billings in July 2019. Ex. 6, ¶¶ 16, 18-19.

IV. Findings of Fact

A. Severity

The threshold issue to be resolved is whether Ms. Cross has demonstrated that she suffered "residual effects or complications of" the injury alleged injury "for more than six months after the administration of the vaccine," as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

As Respondent points out, there is a six-month temporal gap in Petitioner's treatment for her left shoulder symptoms - between October 22, 2018 and April 21, 2019. ECF No. 29 at 10. He also maintains that Petitioner has not introduced corroborating documentation or expert testimony linking her left shoulder pain from September 2018 to her complaints in April 2019, and notes that Ms. Schneider, a physician's assistant, questioned whether a vaccination could cause this type of injury and thought it likely to be "more associated with her job and overhead lifting." *Id.* at 11(citing Ex. 5 at 8). Respondent also points out that Petitioner did not report shoulder pain to the providers she saw in the interim time period. *Id*. at 10.

Respondent's contentions have merit, but are overcome by a review of the record in its totality. The record demonstrates that Petitioner immediately experienced post-vaccination pain, and then consistently reported the onset of her shoulder pain as following her flu shot, including at her April 21, 2019 appointment (the first treatment instance after the gap). Ex. 5 at 7, 16. Moreover, the six-month gap in Petitioner's treatment for her shoulder is at least partially explained by the fact that she received a cortisone injection on October 22, 2018, for her shoulder pain, which subsequently provided significant relief for a period of time. Ex. 4 at 51; Ex. 5 at 7, 16. Additionally, during the gap Petitioner relocated from California to Montana, receiving limited professional care of a specialized nature,[4] while attempting to manage her pain on her own. Ex. 6, ¶¶ 13-14.

Finally, the record does not reflect that Petitioner's shoulder pain in the Spring of 2019 was distinct from her post-vaccination shoulder pain in the Fall of 2018. Despite Ms. Schneider's speculation that Petitioner's shoulder pain might have been caused by her work/overhead lifting, the record convincingly evidences Petitioner's shoulder pain originated with her September 2018 flu vaccination, and there is no evidence of an alternate cause or a new injury.

Based on the record as a whole, there is preponderant evidence that Petitioner's shoulder injury and residual effects thereof persisted for more than six months, and therefore severity is established. (I note, however, that the lengthy treatment delay is evidence that Petitioner's SIRVA was manageable without medical intervention for a significant period of time – and therefore any pain and suffering sum to be awarded in this case may take this into account).

B. Injury Limited to Shoulder

The second disputed issue is whether Ms. Cross's "[p]ain and reduced range of motion are limited to the [left] shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

Respondent points to several records, beginning with Petitioner's first post-vaccination medical encounter, that indicate that Petitioner's shoulder pain "radiated" from her shoulder down her arm, to her elbow, over her shoulder blade, to the neck, and/or her palm. ECF No. 29 at 9 (citing Petition, ¶ 8; Ex. 4 at 50, 54; Ex. 5 at 7). Respondent agues

[4] In addition, it is not surprising that Petitioner's shoulder pain was not documented in her December 2018 VA appointment - as this was a nursing appointment aimed at establishing certain baseline health screening information (related to alcohol, depression, prescription), and did not involve a physical examination. Nor would I necessarily expect Petitioner to discuss her shoulder pain at her mammogram appointment on March 19, 2020, Ex. 2 at 109, or her Billings Clinic appointment the following day, which was specific to an acute rash and abnormal vaginal bleeding. Ex. 5 at 22-29.

that these "instances of radiating arm, pain, and neck symptoms are inconsistent with SIRVA." *Id.* [5]

Petitioner, however, argues that these records demonstrate she subjectively experienced pain in her left shoulder (the site of her vaccination) that was so severe that she felt as if the pain radiated *out* from her shoulder – even though the shoulder was its primary emanating situs. ECF No. 30 at 4-7. Petitioner further observes that her examinations consistently found reduced range of motion limited to her left shoulder, and that there is no evidence of reduced range of motion, or injury, in any other part of Petitioner's body. *Id.* at 7.

Petitioner also argues that in promulgating 42 C.F.R. § 100.3(c)(10)(iii), the Secretary of Health and Human Services (the "Secretary") intended that pain outside the shoulder, to the back or neck, "with an injury to the shoulder in which the individual received a vaccine could still be considered SIRVA." *Id.* at 7-8. This argument warrants some weight. As I observed in *K.P. v. Sec'y of Health & Hum. Servs*., No. 19-0065V, 2022 WL 3226776, at *8 (Fed. Cl. May 25, 2022), in establishing that criterion, the Secretary of Health & Human Services (the "Secretary") emphasized that a SIRVA must only be "*localized* to the shoulder in which the vaccine is administered." Revisions to the Vaccine Injury Table on Jan. 19, 2017, 82 Fed. Reg. 6294, 6296 (emphasis added). Although this wording may be more restrictive than stating, for example, that a SIRVA must "originate" or be "centralized" at the shoulder, additional commentary on the criterion allows for a slightly broader reading. The Secretary has also observed that the criterion is intended to advance a definition of SIRVA as a musculoskeletal condition caused by intramuscular vaccine administration into the shoulder, which must include an injury to the shoulder, and excludes a claim for "pain in the neck or back *without* an injury to the shoulder." *Id.* (emphasis added).

[5] Respondent does acknowledge that Petitioner ultimately underwent an EMG on March 25, 2020, that demonstrated medial nerve abnormalities (consistent with carpal tunnel), but no indications of neuropathy, radiculopathy, or plexopathy. ECF No. 29 at 9, n.1 (citing Ex. 8 at 192; Ex. 10 at 17). Respondent somewhat dismisses the negative EMG findings, however, as Petitioner's EMG occurred 11 months following her last report of radiating pain. *Id.*

Additionally, I note that Respondent does not contend that Petitioner's medial nerve abnormality was a condition or abnormality "that would explain the patient's symptoms" in contravention of the fourth QAI requirement, nor do I find it to be. 42 C.F.R. § 100.3(c)(10)(iv). Rather, Petitioner's medial nerve abnormality is more likely than not a coexisting condition unrelated to Petitioner's shoulder injury or September 2018 vaccination. Additionally, that EMG finding was noted to be asymptomatic. Ex. 10 at 23-24. I have previously recognized that a petitioner may be able to distinguish the evidence supporting a Table SIRVA from "simultaneous areas of pain due to unrelated conditions." *Rodgers v. Sec'y of Health & Hum. Servs*., No. 18-0559V, 2021 WL 4772097, at *8 and n. 16 (Fed. Cl. Spec. Mstr. Sept. 9, 2021).

Accordingly, claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body, since the essence of the claim is that a vaccine administered *to* the shoulder *primarily* caused pain there.[6] This reading has support in the determinations of other special masters. *Grossmann v. Sec'y of Health & Hum. Servs*., No. 18-0013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (explaining that the criterion is intended to "guard against compensating claims involving patterns of pain or reduced range of motion indicative of a *contributing etiology* beyond the confines of a musculoskeletal injury to the affected shoulder") (emphasis added). Here, despite the notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology. Thus, I find Petitioner has satisfied the third SIRVA QAI criterion. 42 C.F.R. § 100.3(c)(10)(iii).

To the extent that any sequelae deemed not related to the shoulder pain remain a contested issue, those can be resolved in the context of damages.

V. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. The vaccine administration record reflects the administration site as the left deltoid. Sections 11(c)(1)(A) and (B)(i); Ex. 3 at 1. There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-vaccination injury. 42 C.F.R. § 100.3(c)(10)(i). Her pain began within 48 hours after vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). There is not preponderant evidence of another condition that would explain the symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Petitioner has not pursued a civil action or other compensation. Section 11(c)(1)(E); Ex. 6, ¶¶ 32-33. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

[6] By contrast, a claim alleging pain *only* in the neck after vaccination would not be a valid SIRVA, absent proof of pain initially and/or primarily in the shoulder.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master